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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,132	10/29/2001	Donald E. Bobo JR.	CVG-5637	2468

7590 02/22/2007  
Debra D. Condino  
Edwards Lifesciences LLC  
Law Department  
One Edwards Way  
Irvine, CA 92614

EXAMINER
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SHAY, DAVID M

ART UNIT	PAPER NUMBER
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3735

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/22/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/021,132

Applicant(s)

BOBO, DONALD E.

Examiner

david shay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 36-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____                                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____   | 6) <input type="checkbox"/> Other: ____                           |

Applicant argues, with respect to the new matter rejection, that the language in paragraph [151] provides support for the amendatory language. While this passage does provide support for sealing the opening in the septum and creating a channel in the surface of the heart chamber, the examiner must note, however, that this cited passage makes no mention of “supportively engaging the medicament delivery catheter with the atrial septum” as the catheter, which sealably engages the septum is not the medicament delivering portion of the device. The originally filed disclosure nowhere discusses a “medicament delivery catheter”, rather the terms system or device are used to describe the medicament delivery and tissue removal portion of the device. Thus the rejection under 35 USC 112, first paragraph has been maintained.

Applicant argues that Flaherty et al does not anticipate the claims to which it has been applied because the balloon is configured to release medicament and therefore cannot constitute a seal. The examiner must respectfully disagree. Flaherty et al clearly wish to avoid washout, just as applicant does (see column 2, lines 55-64) and expressly teaches that the balloon need not be porous (see column 2, lines 11-18). Thus the balloon of Flaherty et al clearly seals the passage. Thus it is unclear how applicant can assert that the balloon does not seal the tissue when pressure is applied thereto by the balloon. Additionally, as set forth before, the mere fact that medicament can leak out slowly does not prevent the balloon from maintaining pressure.

Regarding the rejections under 35 U.S.C. 103, applicant argues that even “if it were possible to physically combine the elements of the four references...” the examiner has not identified any specific evidence in the prior art of motivation to combine. The examiner must first point out that it is well understood that the test for obviousness is not whether the features of one reference may be bodily incorporated into the other to produce the claimed subject matter

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but simply what the combination of references makes obvious to one of ordinary skill in the pertinent art (In re Bozek, 163 USPQ 545 (CCPA)). Secondly, applicant's attention is respectfully invited to the statement of motivation in the rejection of claims 36-38, which is reproduced here for applicant's convenience: "It would have been obvious to the artisan of ordinary skill to, **in order to access the myocardium transvenously**, to employ the method of Jenkins et al, since **Flaherty et al teach no details of the transvenous placement method**; and **in order to wedge the probes** as in the method of Jenkins et al, **to employ the balloons of Kalloo et al, since this would both stabilize the devices as well as seal the opening**, which is desirable, **since this prevents bleeding when the procedure is performed on a beating heart, as taught by Cox et al**, thus producing a device and method such as claimed" (emphasis added). As can readily be seen, the examiner has provided reasons for the combination for the various features. Continuing, applicant proceeds to note that Flaherty et al do not provide the teachings of Jenkins et al. However, since Jenkins et al provide these teachings, it is not necessary for Flaherty et al to provide them as well. Applicant then argues that Cox et al teaches different means of sealing the tissue than that proposed by the examiner. While this may be so, the examiner respectfully notes that Cox et al is used to teach the desirability of providing the seal, not the means of sealing. One of ordinary skill in the art would readily understand that the sealing means of the open chest method of Cox et al could not be easily implemented in the transvenous approach of Flaherty et al and Jenkins et al. Thus a sealing means which is compatible with a transluminal approach, such as that taught by Kalloo et al, would be sought by one having ordinary skill. In short, applicant cannot rebut the examiner's combination by noting all the portions of each reference that are not employed in the combination, completely

disregarding the teachings of the references that one of ordinary skill in the art would employ, as set forth in the statement of motivation.

With regard to the rejection under 35 U.S.C. 103 of claims 39 and 40, applicant alleges that the examiner has engaged in impermissible hindsight. The examiner must respectfully disagree. As can readily be seen from the examiner's motivational statement, which is reproduced herein for applicant's convenience: "It would have been obvious to the artisan of ordinary skill to **employ the combined drug injection of method of Flaherty et al and Jenkins et al** in the method of Mueller ('523) since this **is desirable to help maintain the channels, as taught by Flaherty et al**, thus producing a method such as claimed" (emphasis added, see Flaherty et al column 13, line 53 to column 14, line 8, et seq.), no impermissible hindsight has been employed to make the combination. Further, as set forth above the balloon of Flaherty et al need not be permeable. However, there is no destruction of the Flaherty et al method even in the embodiment with the permeable balloon, as the vacuum fixation device of Mueller et al would not draw the medicament from the balloon, since as clearly shown in Figure 6 of Flaherty et al, the balloon is well inside the passage, which passage would collapse around the catheter upon the application of a vacuum to the surface in which the passage is formed.

The arguments drawn to claim 41 are not convincing for the reasons set forth above.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The amendment filed September 2, 2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not

supported by the original disclosure is as follows: “supportively engaging the atrial septum with the medicament delivery catheter ...”

Claim 36-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed disclosure and the disclosure or amended is silent on “supportively engaging the atrial septum with the medicament delivery catheter ...”

Claims 42-44 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Flaherty et al.

Claims 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flaherty et al in combination with Jenkins et al, Cox et al, and Kalloo et al. Flaherty et al teach a method of myocardial drug delivery. Jenkins et al teach a method of crossing the septum as claimed (column 1, line 20 to column 2, line 54). Cox et al teach the use of means to seal the tissue around an internal chamber ablation device to prevent bleeding when working on a beating heart. Kalloo et al teach the use of a dual balloon stabilizing means to aid in the placement of a surgical device. It would have been obvious to the artisan of ordinary skill to, in order to access the myocardium transvenously, to employ the method of Jenkins et al, since Flaherty et al teach no details of the transvenous placement method; and in order to wedge the probes as in the method of Jenkins et al, to employ the balloons of Kalloo et al, since this would both stabilize the devices as well as seal the opening, which is desirable, since this prevents bleeding when the

procedure is performed on a beating heart, as taught by Cox et al, thus producing a device and method such as claimed.

Claims 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flaherty et al in combination with Jenkins et al, and Mueller ('523). The teachings of Flaherty et al and Jenkins et al and the motivations for combination thereof are substantially as set forth above. Mueller ('523) teach sealing to the cardiac tissue using a vacuum port before creating a channel in the tissue. It would have been obvious to the artisan of ordinary skill to employ the combined drug injection of method of Flaherty et al and Jenkins et al in the method of Mueller ('523) since this is desirable to help maintain the channels, as taught by Flaherty et al, thus producing a method such as claimed.

Claims 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Flaherty et al in combination with Jenkins et al, and Mueller ('523) as applied to claims 39 and 40 above, and further in view of Jeevanandam et al. Jeevanandam et al teach the use of multiple vacuum ports to secure a channel-forming device to the cardiac wall so as to form chambers therein. It would have been obvious to the artisan of ordinary skill to provide multiple ports, as taught by Jeevanandam et al, since this provides secure fixation and to provide four ports, since the number of ports can be varied as desired, as taught by Jeevanandam et al, thus producing a method such as claimed.

Applicant's arguments filed November 30, 2006 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant's arguments with respect to claim <sup>§ 36-44</sup> ~~1~~ have been considered but are moot in view of the new ground(s) of rejection. *dm*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

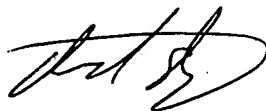


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II, can be reached on Monday, Tuesday, Wednesday, Thursday, and Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID M. SHAY  
PRIMARY EXAMINER  
GROUP 330